Remarks

Claims 36, 38, 39, 41, 42, 46, 47, 49, 50, and 57 are amended. New claims 66-79 are added. Claim 1-35, 37, 44, 45, 51, 52, 54-56, 58, and 62-65 are cancelled. As a result, claims 36, 38-43, 46-50, 53, 57, 59-61, 66-79 are presented for the Examiner's review and consideration. Applicant believes the amendments and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Telephonic Interview

Applicant appreciates the courtesies extended to Applicant's representative, Alice Martin, during the telephonic interview with Examiner Ramana on January 27, 2009 and February 3, 2009. After careful consideration, Applicant submits this Response. Applicant respectfully submits that this Response satisfies the requirements of MPEP §713.04 and is fully responsive to the outstanding Office Action.

Amendment to the Specification

No new matter has been added by the amendment to the title made herein. This amendment has been made only so that the title of the application coincides with the invention as currently claimed.

Amendments to the Claims

It is noted that the references to the application made herein are meant only to represent examples of support for amendments, and are not a comprehensive list of support. The amendments to the claims and arguments presented throughout this Response may be supported in other parts of the application that are not referenced.

No new matter has been added by the amendments to the claims made herein. Examples of support for these amendments are presented below.

No new matter has been added by new claims 66-79. The subject matter of new claim 66, which depends from claim 57, is supported by FIG. 14D and associated text. The subject matter of claim 67, which depends from claim 36, is supported at page 7, lines 7-14.

New claims 68-79 have been added and are directed to another aspect of the invention. Should the Examiner find claims 68-79 allowable (or a subset thereof), Applicant would consider cancelling the rest of the claims.

Claim 68 is directed to a method of using body tissue and is fully supported by the specification as-filed as follows, with citations to the specification identified in parentheses. Claim 68 includes the steps of moving at least a portion of a shaft of an elongate member through a percutaneous incision in a donor (support identified below and previously identified in prior Responses) such that a leading end of the shaft is located within cortical confines of a bone (page 4, lines 17-20); removing body tissue from the donor through the percutaneous incision (page 3, lines 18-20), wherein the removed body tissue is removed from within the bone, contains viable cells, and is substantially free of hard bone (page 4, lines 17-20 and page 21, lines 2-10); conveying the removed body tissue along a passage in the shaft under the influence of suction (page 2, lines 24-26); and implanting at least one component of the removed body tissue in a patient (page 21, lines 7-14), wherein the at least one component includes viable cells (page 21, lines 2-12) and is maintained sterile until implantation (page 7, lines 10-14).

Claims 69-79, which depend from claim 68, are analogous to dependent claims either currently pending or previously presented.

The Written Description and Enablement Requirements Are Satisfied

In the Final Office Action, claims 36, 38-50, 52-55, and 57-65 were rejected as failing to comply with the written description and enablement requirements.

Claim 36 is amended. The other remaining claims rejected under Section 112 are dependent on amended claim 36. *In haec verba* support is not required to pass the written description requirement. The disclosure must convey to a person of skill in the art that the inventor had possession of the invention. Support in the present record expressly shows that

fetal tissue was included in the scope of the invention; that tissue was to be removed avoiding damage to vital organs; and harvesting tissue for reuse (transplantation) into a patient was extensively described.

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding Inc*., 230 F.3d 1320, 1323 (Fed. Cir. 2000) (*citing Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996)).

Ipsis verbis disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996).

If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in ipsis verbis [i.e., "in the same words"] to be sufficient"). MPEP 2163, 8th Ed. Rev. 6 (2008).

The Examiner admits (Office Action pages 8-9):

> …the only language pertinent to the method steps of claims 36, 63 and 56 are:
>
> At page 3, lines 5-12 "and to avoid vital tissue which could otherwise be in the cutting path. For example, when removing unwanted tissue inside a knee joint the drill shaft can deform, and is therefore less likely to damage normal tissue or joint surfaces. None of these functions is possible with a straight line system."
>
> At page 3, lines 18-20: "The invention is not limited to the removal of bone tissue and may be used for removal of cartilage, muscle, fetal tissue, etc."
>
> At page 7, lines 7-14: "Thus, the tissue fragments are not merely removed from the body and may be harvested for implantation of

> the fragments, preferably, into the body of the patient from whom they are removed."
>
> At page 8, lines 3-6: "Human tissue grafting works best using the patient's own tissue as donor material. Therefore, the harvested tissue may be implanted in the donor's own body for grafting."
>
> At pages 9, lines 5-11: "The method may further include the step of controlling the location of the cutting tip within the tissue with a guide rod, the step of collecting one or more selected components of the harvested tissue fragments, and/or the step of implanting the fragments into the body of the patient from whom they were removed."
>
> At page 11, lines 20-24: "It should be understood that the present invention is not limited to the removal of bone tissue, but is useful in the removal of any hard or soft tissue in the body such as excess, unwanted, or tumorous tissue used for reimplantation or grafting."
>
> At page 21, lines 7-14: The harvested tissue fragments are not merely removed from the body of the patient, but are also collected in the structure 28 and this harvested or saved for later implantation of the fragments, preferably into the body of the patient from whom they are removed. Such harvesting and implantation are desirable because human tissue grafting works best using the patient's own tissue as donor material."

Those of skill in the art would understand that in order to transplant cells into a donor, as repeated throughout and acknowledged by the Examiner, methods known to those of skill in the art to preserve viability of removed donor's cells would be used. Well known methods such as preserving and culturing cells need not be described in detail in a patent application to satisfy enablement.

There is no need to expressly describe methods to preserve and culture cells for transplantation of fetal tissue into a patient because preservation and cell culture methods were well known in 2001, the filing date of the present application. In fact, the Federal Circuit discouraged disclosure of information available to those of skill in the art. For example,

> a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the

> disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. ……. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly, we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation …of such genes and sequences. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006).

The clearly expressed intent of the invention is not to damage the donor of the tissue sample that is obtained by means of the methods and apparatus disclosed. Donors of the fetal tissue are fetuses by definition. The apparatus was developed to safely remove tissue from the donor and obtain viable tissue for use, preferably in the donor. An advantage of the apparatus of the present invention over other apparatus that are only capable of straight line entry is "to avoid vital tissue which would otherwise be in the cutting path." (page 3, lines 5-8)

Although Applicant does not agree that the previous claims did not satisfy the Written Description requirement, claims are amended to use terms the Examiner agrees are in the specification, and some claims are cancelled to simplify issues in prosecution.

Other support for present amendments includes:

> At page 1, lines 5-10: "The present invention relates to the field of tissue removal and tissue grafting … removal and the possible harvesting and implantation of the tissue portion in the donor."
>
> On page 5, line 5, "removal apparatus."
>
> At page 7, lines 10-14: "In order to maintain the sterility of the tissue removed, the entire suction apparatus including the suction passage and the trap or filter is sterilized, and, if necessary, is disposable."
>
> At page 16, lines 23-26: "The disposable single-use liner sleeve 110 provides an absolutely sterile environment through which harvested tissue fragments may pass."
>
> At page 21, lines 2-10: "Removed tissue may also be centrifuged if necessary or desired, keeping the components such as bone, cells, and blood and discarding fluid. These components and

> connections, and their uses, are well known in the art and thus are not described herein in greater detail. The harvested tissue fragments are not merely removed from the body of the patient, but are also collected in the structure 28 and thus harvested or saved for later implantation of the fragments."

Other manifestations in the specification argued for previous claims relating to the intent not to harm the donor or tissue from the donor include:

"Because the drill shaft is flexible…to avoid vital tissue which would otherwise be in the cutting path." (page 4, lines 11-17)

"Fluid may be injected…to limit thermal necrosis." (page 6, lines 19-22)

"…to minimize the damage to skin, muscle and bone." (page 7, line 17)

"The goals to be met are proper cutting and sectioning capabilities, controllability and shape so as to avoid unwanted damage to areas of tissue not to be cut." (page 18, lines 10-13)

Minimize bleeding (example, bone tissue) (page 7, lines 15-27 to page 8, lines 1-2).

Fetal tissue may be collected, cultured and stored for future implantation in the fetus after birth. "The tissue fragments are not merely removed from the body, and may be harvested for implantation of the fragments, preferably into the body of the patient from which they were removed…" (page 7, lines 7-10.)

When the tissue is fetal tissue, the "body" from which the tissue is removed is the fetus, and implantation is contemplated preferably in the fetus, generally after birth, but other recipients are not excluded. (page 2, lines 24-26; page 3, lines 1-2.)

Human tissue grafting works best using the patient's own tissue as donor material." (Page 8, lines 3-4).

"The harvested tissue fragments are not merely removed from the body of the patient, but are also collected in the structure 28 and thus harvested or saved for later implantation of the fragments, preferably into the body of the patient from whom they were removed." (page 21, lines 7-10).

The Examiner states that "maintaining fetal tissue viability" is not enabled. Applicant has not only expressly taught sterility and irrigation, but those of skill in the art of tissue culture would not need further guidance to maintain and culture cells.

In both the Advisory Action mailed January 30, 2009 and the Supplemental Advisory Action mailed February 6, 2009, the Examiner stated that the un-entered Response filed December 29, 2009 overcame the rejections under the first and second paragraph of 35 U.S.C. § 112. Although Applicant has made further claim amendments to clarify the present invention, Applicant respectfully submits that these rejections should still be considered overcome.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 112, first and second paragraphs (written description and enablement).

Publications Cited As Anticipating Do Not Teach All Claim Elements, Therefore Do Not Anticipate Or Support an Obviousness Rejection

Claims 36, 38, 39, 54, 57, 58 and 59 were rejected under 35 U.S.C. §102(b) by Martin (US 4,756,708).

To anticipate, Martin must teach each claim element, and it does not. Indeed, Martin discloses a catheter, not an apparatus capable of percutaneous insertion as in the present invention, where the access to fetal tissue is through a puncture. This is clear because a fetus is not directly accessible by a catheter. No puncturing is taught by Martin.

> The object of this procedure is to remove, by vacuum, a sample of the villi and assay the sample to determine the genetic health of the fetus. This procedure requires a physician to insert a thin catheter through the vagina and cervix into the uterus ending at the chorion membrane. When the catheter tip is located on the villi, a source of negative pressure is coupled to the catheter to withdraw a sample of villi tissue for analysis.

Martin, page 4.

Also, chorionic villi (from the placenta) are not transplanted back into a donor. Also, the CVS sample is not collected under sterile conditions, as taught in the present application. The

placenta develops from the chorion of the embryo and the decidua basalis of the mother. It is not from one source, so there is no single "donor".

Should the rejection of claim 36 as anticipated by Martin be maintained, Applicant respectfully requests identifying of the disclosure in Martin that teaches the steps of "inserting a removal apparatus into a donor through a percutaneous incision" and "implanting the separated portions of fetal tissue in a patient."

Claims 36, 40-42, 44 and 54 were rejected as anticipated by Golbus et al.

Golbus teaches a "26- or 27-gauge needle…" to puncture the "fetal umbilical cord or placental surface vessels." (Golbus, p. 423); a "22 - or 25 - gauge spinal needle" for fetal blood sampling; use of "16.5 gauge thin wall Lee biopsy needle" for fetal liver biopsies. (Golbus, p. 423) 0.9% saline was used to flush the liver biopsy out of a 3 ml syringe attached to the needle to remove tissue by negative suction.

Golbus, like Martin, teaches obtaining samples to use for fetal diagnosis, not for transplantation. Neither reference implants the separated portions of fetal tissue in a patient as in the present invention.

The Examiner correctly quoted from *Ex parte Pfeiffer*, but the Board in this case specifically reaffirmed that 35 U.S.C. 100(b) impliedly permits recitation of structure in method claims, the issue against which the USPTO Examiner argued as long as they are manipulative.

Structural steps in present claims are manipulative because they are necessary to preserve fetal tissue viability for harvesting and transplantation, and are distinct. The structural limitations of claim 36 are not "uncontrolled operation", the reason the court in *Pfeiffer* gave to rule that the structural limitations added to rejected method claim in that case, did not confer patentability. If we could move toward allowance by incorporating more structural elements Applicant could consider additions.

A Prima Facie Case of Obviousness is Not Established

The Examiner has not established a prima facie case of obviousness for any of the following rejections. "[A] patent composed of several elements is not proved obvious merely by

demonstrating that each of its elements was independently known in the prior art." *KSR*, 127 S.Ct. at 1741.

Claims 40-42 were rejected under 35 U.S.C. § 103(a) over Martin and Siegmund.

Martin has been discussed above. The Examiner offers Siegmund to supply the elements "suction" and "irrigation" which the Examiner admits are missing in Martin.

The Examiner also admits Martin does not teach "a syringe with a built in filter for collection of tissue fragments or cells." (Office Action, page 6). The Examiner uses Molomut to supply that missing element to yield claim 43.

Claims 38-40, 42-43 and 57-61 were rejected over Martin and Weaver (US 4,245,653). The Examiner admits Martin does not teach "the use of a flexible apparatus …" (Office Action, page 9) and offers Weaver to supply that deficiency.

Finally, claim 52 was rejected over Golbus with O'Neill (US 4,486,209). Golbus has been discussed above. O'Neill was used to supply x-ray or ultrasound guidance.

If biopsy devices were interchangeable, as the Examiner argues, to make the present claims obvious, there would not be so many devices, covered by so many patents.

Also, according to *KSR*, there still must be an apparent reason to combine the known elements in the fashion claimed by the patent at issue. "To facilitate review, this analysis should be made explicit." (*Id* at 1741) As directed in the MPEP:

> To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.

MPEP § 706.02(j) quoting *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

A determination of obviousness requires that "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *KSR International Co. v. Teleflex, Inc.*, U.S., 127 S.Ct. 1727, 1734, 82 U.S.P.Q.2d 1385 (2007) quoting *Graham v. John Deere Co.*, 383

U.S. 1, 17 (1966). In making a determination of obviousness by looking at the teachings of multiple patents, one should consider:

> …the effects of demands known to the design community or present in the market place; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

KSR, 127 S.Ct. at 1740-41 (*emphasis added*).

The Examiner has not provided explicit evidence that the various groupings of publications cited in support of obviousness, would indeed be combined by those of skill in the art. Furthermore, both the Advisory Action mailed January 30, 2009 and the Supplemental Advisory Action mailed February 6, 2009, assert that if "claim 36 is amended to positively recite the steps of harvesting and transplantation, claim 36 could be rejected over prior art related to fetal tissue engineering, for e.g. where fetal tissue is harvested using a minimally invasive technique and is then transplanted back into the fetus upon delivery of the fetus for treatment of a prenatally diagnosed birth defect." Now that claim 36 has been amended in an analogous fashion, Applicant respectfully requests identification of this prior art.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Conclusion

In light of the foregoing amendments and remarks this application is now in condition for allowance, and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned. The fee for a request for continued examination pursuant to Section 1.17(e) in the amount of $405 is believed to be due and is being paid via credit card. No other fees are believed to be due at this time. However, please charge any other fee required (or credit any

overpayment) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A02-014-7).

Respectfully submitted,

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